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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sang Yup Lee

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

JUNG, UNSU

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,261	Applicant(s) LEE ET AL.	
	Examiner UNSU JUNG	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/1/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments in the reply filed on May 21, 2009 have been acknowledged and entered. The reply included amendments to claim 1 and cancellation of claims 2 and 3.

Status of Claims

2. Claims 1 and 4-10 are pending, claims 8 and 10 have been withdrawn from consideration, and claims 1, 4-7, and 9 are currently under consideration for patentability under 37 CFR 1.104.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is the U.S. national stage application of International PCT Application No. PCT/KR2003/002183, filed on October 18, 2003, which claims the priority of Korean Patent Application Serial No. 10/2003/0000464, filed on January 4, 2003. The certified copy of Korean Patent Application Serial No. 10/2003/0000464 has been filed in the instant application.

Information Disclosure Statement

4. In view of the Bradford reference provided in the reply filed on May 21, 2009, the information disclosure statement filed on July 1, 2005 has been reconsidered with the Bradford reference.

Rejections Withdrawn

5. The following rejections have been withdrawn in view of the amended independent claim 1 in the reply filed on May 21, 2009:

- Rejection of claims 1-7 and 9 under 35 U.S.C. 112, second paragraph;
and
- Rejection of claims 1, 6, 7, and 9 under 35 U.S.C. 102(b) as being anticipated by Duffy (U.S. PG Pub. No. US 2002/0028463 A1, Mar. 7, 2002).

New Grounds of Rejections

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following prior art rejections has been modified (**bolded passages**) due to amendment of independent claim 1 in the reply filed on May 21, 2009.

9. Claims **1 and 4-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over MacBeath et al. (*Science*, Sept. 8, 2000, Vol. 289, pp1760-1763) (hereinafter "MacBeath") in view of Inglese et al. (U.S. Patent No. 6,335,176 B1, Jan. 1, 2002) (hereinafter "Inglese").

With respect to claims 1 and 5, MacBeath teaches protein microarrays (protein chips) for high throughput function determination (see entire document). A variety of chemically derivatized slides (solid substrate) can be printed for example slides treated with aldehyde-containing silane reagent. The aldehydes can react readily with primary amines on the proteins. Protein microarray offer an ideal system, for example, for the rapid and parallel identification of substrates of protein kinases using protein microarray spotted with protein substrates such as kemptide (substrate peptide, p1762, 1st column, 2nd paragraph).

With respect to claim 6, MacBeath teaches a method for analyzing interaction between a reactive protein and the substrate peptide comprising the steps of:

- adding a reactive protein to the protein chip, the reactive protein showing a specific interaction with the substrate peptide immobilized on the protein chip (p1762, 2nd paragraph); and
- detecting the interaction between the reactive protein and the substrate peptide (p1762, 2nd paragraph).

However, MacBeath is silent on teaching that the substrate peptide is immobilized on the solid substrate by the mediation of a linker protein.

Inglese teaches reagents for incorporating phosphorylation sites into compounds, particularly into proteins (linker protein) and peptides (see entire document, particularly column 2, lines 11-26). The reagents include a peptide sequence that contains kinase substrate (column 2, lines 11-19) including “kemptide” sequence, LRRASLG (column 7, line 67). The resulting compound is useful for many types of assays including high

throughput screening assays (column 10, lines 6-11). **Inglese further teaches the linker protein comprises leptin (column 13, lines 26-51).**

With respect to claims 1 and 4, Inglese teaches the substrate peptide comprises kemptide (SEQ ID NO: 1).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the reagents of Inglese, which includes proteins linked to substrate peptides, in the protein microarray of MacBeath in order to immobilize small substrate peptides. The advantage of allowing small substrate peptides linked to protein molecules to be attached to the protein microarray surface without being obscured by BSA molecules, which are used to reduced nonspecific binding of other proteins by quenching unreacted aldehydes on the protein microarray surface as taught by MacBeath (p1760, 5th paragraph-p1760, 1st paragraph), provides the motivation to combine teachings of MacBeath and Inglese with a reasonable expectation of success.

10. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacBeath (*Science*, Sept. 8, 2000, Vol. 289, pp1760-1763) in view of Inglese (U.S. Patent No. 6,335,176 B1, Jan. 1, 2002) as applied to claims 1 and 6 above, and further in view of Duffy (U.S. PG Pub. No. US 2002/0028463 A1, Mar. 7, 2002).

MacBeath in view of Inglese teaches a method of analyzing the interaction between a reactive protein and its substrate peptide using a protein chip of S-L-

SP form as set forth above. However, MacBeath in view of Ingles fails to teach that the reactive protein is a fluorescent labeled antibody.

With respect to claims 7 and 9, Duffy teaches a protein chip of a S-L-SP form (see entire document, particularly Fig. 4), wherein a substrate peptide (SP, p5, paragraph [0046]) is immobilized on a solid substrate (S, array) by the mediation of a linker protein (L, streptavidin, p10, paragraph [0091] and Fig. 4). Duffy further teaches a method, wherein the reactive protein is an antibody labeled with fluorescent tags (pp4-5, paragraph [0038]).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the fluorescent labeled antibody of Duffy as the reactive protein in the method of MacBeath in view of Ingles in order to detect the binding of the reactive protein to the substrate peptide. The advantage of directly detecting the binding of the reactive protein to the substrate peptide provides the motivation to combine teachings of MacBeath in view of Ingles and Duffy with a reasonable expectation of success.

Response to Arguments

11. Rejection of claims 1 and 2-6 under 35 U.S.C. 103(a) as being unpatentable over MacBeath in view of Ingles

Applicant's arguments filed on May 21, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's argument MacBeath and Inglese fails to teach the claimed invention, which includes a substrate peptide immobilized on a solid substrate via a linker protein of leptin or malic enzyme, wherein the substrate protein is fused with the linker protein in the form of a peptide monomer, a dimer of monomer-proline-monomer, or a multimer, where the monomers are linked to each other by a proline has been fully considered but is not found persuasive essentially for the reasons of record. In contrast to applicant's assertion that Inglese does not teach the claimed fusion protein with a substrate protein fused to a linker protein, Inglese does teach a fusion protein, which is formed by linking a kinase substrate to a pre-existing compound such as a protein (column 3, lines 40-48). The protein can include leptin (column 13, lines 26-51), which reads on the linker protein of the claimed invention. Therefore, Inglese does teach the claimed fusion protein with a substrate protein fused to a linker protein.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, MacBeath teaches protein microarrays (protein chips) for high throughput function determination (see entire document) as set forth above and in the previous Office Action dated January 21, 2009 (see item 13). A variety of chemically derivatized slides (solid

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substrate) can be printed for example slides treated with aldehyde-containing silane reagent. The aldehydes can react readily with primary amines on the proteins. Protein microarray offer an ideal system, for example, for the rapid and parallel identification of substrates of protein kinases using protein microarray spotted with protein substrates such as kemptide (substrate peptide, p1762, 1st column, 2nd paragraph). However, MacBeath is silent on teaching that the substrate peptide is immobilized on the solid substrate by the mediation of a linker protein. Inglesse teaches fusion protein with a substrate protein fused to a linker protein as set forth above. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the reagents of Inglesse, which includes proteins linked to substrate peptides, in the protein microarray of MacBeath in order to immobilize small substrate peptides. The advantage of allowing small substrate peptides linked to protein molecules to be attached to the protein microarray surface without being obscured by BSA molecules, which are used to reduced nonspecific binding of other proteins by quenching unreacted aldehydes on the protein microarray surface as taught by MacBeath (p1760, 5th paragraph-p1760, 1st paragraph), provides the motivation to combine teachings of MacBeath and Inglesse with a reasonable expectation of success.

In view of the foregoing response to arguments, the rejection of claims 1 and 2-6 under 35 U.S.C. 103(a) as being unpatentable over MacBeath in view of Inglesse has been maintained.

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12. Applicant's arguments with respect to claims 7 and 9 have been considered but are moot in view of the new ground(s) of rejection as set forth above.

13. Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung
Primary Examiner
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